

EXHIBIT 12

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

In Re:)
)
ZOLOFT (SERTRALINE) MDL No 2342
HYDROCHLORIDE) PRODUCTS)
LIABILITY LITIGATION) 2:12-MD-02342-CMR
)
)
)
)

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10 EXPERT WITNESS TESTIMONY OF
11 NICHOLAS P. JEWELL, Ph.D.
12 CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER
13 Held at the Law Offices of
14 Skikos, Crawford, Skikos & Joseph
15 One Sansome Street, San Francisco, California
16 Tuesday, May 5, 2015, 9:27 a.m.

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REPORTED BY: ELAINA BULDA-JONES, CSR #11720

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1 study, which is a very specific population-based
2 cohort study in Quebec, relates to the comments of
3 Judge Rufe regarding her overall methodology in the
4 Zolofit litigation, which involved, presumably,
5 reviewing the totality of the literature. Which is
6 a very different animal.

7 I do not believe that Judge Rufe said that
8 she was -- there's anything in there to say that her
9 scientific articles would not be credible in her own
10 research area. So without that, I would just take
11 this at face value and recognizing the conflict of
12 interest as much as I would the conflict of interest
13 if there were papers with Pfizer authors on it.

14 BY MR. WOLFF:

15 Q. So when you say that you take this at face
16 value, does that mean that you took the data
17 reported in Dr. Berard's 2015 study at face value?

18 A. I mean I just take the paper. I take the
19 paper for what it is. And then now we've got a
20 newer version than what, I guess, I was looking at
21 back in February when I wrote -- when I was aware of
22 this.

23 I didn't say I shouldn't look at this
24 paper because she's being not accepted as an expert
25 in the Zolofit litigation. I didn't take that as a

1 sign that I should ignore this paper in its
2 entirety.

3 Q. Did you independently assess her data?

4 A. I looked at her -- no, I did not
5 independently assess her data. I looked at her data
6 that was in summary form on, I think, largely in
7 table two of the paper in -- on page -- no,
8 that's -- you know, I can't remember.

9 It was one -- I'm looking at a slightly
10 different version here. Is there a supplement in
11 here? I looked at some of the data. I -- actually
12 the first time I was asked to look at that data was
13 by Pfizer's counsel at the Frye hearing when she
14 requested that I actually analyze data from an
15 earlier version of this that she -- she abstracted
16 and flashed up on a screen or something in the Frye
17 hearing. I don't remember the details.

18 Q. Let's -- let's just sort of, again, in
19 stepwise fashion, in the abstract of the 2015 study
20 Dr. Berard reports that Zolof exposure was
21 associated with an increased risk of atrial
22 ventricular defects specifically with a risk ratio
23 of 1.34, 95 percent confidence interval of 1.02 to
24 1.76 with nine exposed cases --

25 A. Uh-huh.

1 Q. -- and craniosynostosis with a risk ratio
2 of 2.03, a 95 percent confidence interval of 1.09 to
3 3.75 with three exposed cases, correct?

4 A. You read that correctly.

5 Q. And as part of your review of Dr. Kimmel's
6 transcript from the Frye hearing that was held
7 before Judge Bernstein, did you read that portion
8 where Dr. Kimmel addressed with particularity his
9 questions about the accuracy and reliability of the
10 data analysis in Dr. Berard's 2015 study?

11 A. I may or may not have in the transcript,
12 but I certainly -- it's more fresh in my memory,
13 reading his comments in his rebuttal report that we
14 referred to earlier that has a similar -- I think
15 similar set of comments that he reported at the
16 hearing in front of the judge.

17 Q. Okay. Exhibit 30, for your convenience,
18 Dr. Jewell, is a copy of Dr. Kimmel's report.

19 (Whereupon, Exhibit 29 and Exhibit 30 were
20 marked for identification.)

21 BY MR. WOLFF:

22 Q. You are aware that on page 15 and 16 in
23 Dr. Kimmel's recent report he addressed his concerns
24 and included a table based on the data that
25 Dr. Berard includes in table two of her study,

1 correct?

2 A. Yes, I've looked at this. It was in the
3 last couple weeks.

4 Q. Right.

5 A. Briefly.

6 Q. Sure. And table two of Dr. Berard's 2015
7 study charts the data on Zoloft, other SSRIs, and
8 birth defects by organ system, correct?

9 A. It does. That is correct. These are
10 large groupings of -- of malformations.

11 Q. Just focusing on Zoloft, the only two
12 findings that are statistically significant, based
13 on the 95 percent confidence intervals, would be
14 ventricular atrial septal defects and
15 craniosynostosis, correct?

16 A. They are not -- like I said, we're over
17 the page now. Yes, they are over the page on page
18 E6. Just focusing on sertraline, yes, ventricular
19 atrial septal defect, the one that you already read
20 from the abstract, and the craniosynostosis also
21 that you read from the abstract.

22 It's significant in the adjusted analysis,
23 not in the crude -- almost very close to significant
24 in the crude.

25 Q. Now, while we cannot be sure precisely how

1 Dr. Berard calculated her adjusted risk ratios,
2 because we do not have her data on the confounders
3 that she controlled for, table two presents enough
4 basic data to double-check her risk ratios and 95
5 percent confidence intervals with respect to the
6 crude data, correct?

7 A. No, that's incorrect.

8 Q. Why is that incorrect?

9 A. Because you need the raw data to check --
10 not to check the risk ratios, perhaps, though even
11 that is a little unsure. But you don't have enough
12 information probably to get the confidence intervals
13 from the paper.

14 Q. Well, if you take a look at page 16 of
15 Dr. Kimmel's report --

16 A. Uh-huh.

17 Q. -- he used the two-by-two table on
18 openepi.com. Now, OpenEpi is an open
19 source software that you use, correct?

20 A. I use it occasionally and I think we -- I
21 discussed it at a previous deposition that I use it,
22 yes.

23 Q. Yes. And by -- if we take a look at the
24 entries in white and compare them with the entries
25 in yellow --

1 A. Uh-huh.

2 Q. -- but for the 95 percent confidence
3 intervals for ventricular atrial septal defects and
4 craniosynostosis, both the odds ratios and the
5 confidence intervals for all of the findings are
6 consistent, with the possible exception generally
7 down to the hundredth place, correct?

8 A. Second decimal place.

9 Q. Second decimal place.

10 A. Yep.

11 Q. And --

12 A. That's not quite true for the nervous
13 system. That's the second decimal place, yes --
14 second decimal place, yes. That's what I -- I think
15 that's reasonable. You got a .98 going up to 1.02,
16 but they're very similar in all but two cases, I
17 think.

18 Q. And if we take a look at the entry for
19 ventricular atrial septal defects --

20 A. Yes.

21 Q. -- the 95 percent confidence interval
22 changes from 1.01 to 1.79 to 0.69 to 2.65?

23 A. That is correct. In -- in Dr. Kimmel's
24 calculation on OpenEpi.

25 Q. And properly calculated that risk ratio is

1 no longer statistically significant under the
2 OpenEpi results?

3 MR. ZONIES: Object to the form.

4 BY MR. WOLFF:

5 Q. Correct?

6 A. Assuming the OpenEpi results are the right
7 thing to do for this data. Which is actually
8 incorrect. But that's -- that's what Dr. Kimmel
9 failed to recognize.

10 Q. Why -- why do you say that the OpenEpi
11 data are incorrect?

12 A. Because neither you nor Dr. Kimmel read
13 the statistical section, apparently, in Dr. Berard's
14 report where she specifically highlights that that's
15 not what she did or her statistician did.

16 So, you know, I was aware of that when
17 been asked at Frye. I knew I couldn't calculate the
18 confidence intervals directly from the two-by-two
19 table and conform with what Dr. Berard says she did.
20 Now, whether what she did is still right or wrong, I
21 can't tell without seeing the raw data.

22 But I do know that Dr. Kimmel's
23 calculations here reflect that he failed to read the
24 statistical section because he deliberately used a
25 method that was different from what Dr. Berard said

1 was used.

2 Q. What --

3 A. Why he did that and didn't comment on it,
4 I can only speculate that he's not a statistician
5 and doesn't take such joy in reading statistical
6 sections as I do.

7 Q. What is it specifically about the
8 description of the statistical analysis in the
9 methods section of Dr. Berard's 2015 study, that
10 leads you to assert that Dr. Kimmel did not
11 appreciate the statistical analysis that was done?

12 A. Well, Dr. Kimmel did two-by-two analysis,
13 by your own description, and I think that probably
14 described -- he computed crude odds ratios using
15 OpenEpi and I assume he just plugged those in to a
16 two-by-two table and hit the button to calculate.

17 MR. WOLFF: We need to take a break to
18 change the tape.

19 THE VIDEOGRAPHER: Thank you. This marks
20 the end of Video Number 3 in the deposition of
21 Dr. Nicholas Jewell. Going off the record. The
22 time is 4:44.

23 (Whereupon, a brief recess was taken.)

24 THE VIDEOGRAPHER: Here begins Video
25 Number 4 in the deposition of Dr. Nicholas Jewell.

1 Coming back on the record. The time is 4:57.

2 BY MR. WOLFF:

3 Q. Dr. Jewell, is a wide confidence interval
4 reflective of the imprecision of the odds ratio?

5 A. As we discussed this morning, yeah, the
6 variability of an estimate is automatically
7 reflected in the width of the confidence interval.

8 Q. Are there hazards of drawing a causal
9 inference from a small data set?

10 A. Well, it depends on the context of that.
11 First of all, you're talking about one data set, so
12 you'd -- you'd like replication. Two, if it's
13 small, the variability is usually high. And so
14 unless you see a very strong effect, you're not
15 going to be able to distinguish an association
16 from -- very effectively from the role of chance.

17 Q. Can you describe the bias known as belief
18 in the law of small numbers?

19 A. I think you'd have to be more explicit
20 than that. I sort of vaguely heard that term, but I
21 would need more explanation, what you mean.

22 Q. I thought this would have been right up
23 your alley, not a question.

24 A. Okay.

25 Q. Okay. Question, isn't the belief in the

1 STATE OF CALIFORNIA)

2 COUNTY OF YOLO)

3 I, ELAINA BULDA-JONES, a Certified Shorthand
4 Reporter of the State of California, duly authorized
5 to administer oaths pursuant to Section 2025 of the
6 California Code of Civil Procedure, do hereby
7 certify that

8 NICHOLAS P. JEWELL, Ph.D.,
9 the witness in the foregoing deposition, was by me
10 duly sworn to testify the truth, the whole truth and
11 nothing but the truth in the within-entitled cause;
12 that said testimony of said witness was reported by
13 me, a disinterested person, and was thereafter
14 transcribed under my direction into typewriting and
15 is a true and correct transcription of said
16 proceedings.

17 I further certify that I am not of counsel or
18 attorney for either or any of the parties in the
19 foregoing deposition and caption named, nor in any
20 way interested in the outcome of the cause named in
21 said deposition dated the _____ day of
22 _____, 2015.

23

24

25 ELAINA BULDA-JONES, RPR, CSR 11720